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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,430	01/07/2009	Eric Mangiardi	047956/307855	4712

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EXAMINER

GRAHAM, BRIAN J

ART UNIT	PAPER NUMBER
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3734

MAIL DATE	DELIVERY MODE
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12/08/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/585,430	Applicant(s) MANGIARDI ET AL.	
	Examiner BRIAN GRAHAM	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-22 and 24-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-22 and 24-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>01/07/2009, 07/07/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7, 13-22, 24-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Derus *et al.*, hereinafter referenced as “Derus” (United States Patent Application Publication Number 2002/0183827).

Derus discloses a device for deploying a stent inside an anatomical lumen of a patient comprising a stabilizing member (66), an outer tubular member (38), an inner tubular member (40), the inner tubular member coupled with the stabilizing member and a portion of the inner tubular member disposed within the outer tubular member such that the inner member is longitudinally and axially displaceable relative to the outer member (see Figure 5a). Derus further discloses a deployment mechanism comprising a release member (68) for moving the outer tubular member longitudinally relative to the inner tubular member without initially disengaging a safety mechanism.

Regarding claim 2, Derus discloses a second release member (72) operably connected to the first release member for moving the second release member and outer tubular member in a direction toward the stabilizing member from a first position to a second position of the outer tubular member relative to the inner tubular member.

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Regarding claim 3, the first release member is movable relative to the second release member (flexing at the joint below the second release member rotates assembly and moves the two release members relative to each other) for moving the first release member and the outer tubular member in a direction toward the stabilizing member.

Regarding claim 4, Derus discloses a safety member (56) for preventing movement of the release member and outer tubular member toward the stabilizing member.

Regarding claim 5, movement of the release member exposes a portion of the stent (see Figure 9).

Regarding claim 7, the safety member comprises a removable tab disposed between the stabilizing member and the outer tubular member (Figure 6 shows the tab of 56 disposed between the distal end of the outer tubular member and the stabilizing member).

Regarding claim 13, Derus discloses a stent (20) slidably disposed in the outer tubular member (see figure 8).

Regarding claim 18, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the exposed portion of the stent be 5-95% of the length of the stent, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claim 25, Derus discloses advancing the release member and the outer tubular member relative to the inner tubular member in a direction toward the stabilizing member (Figures 20 and 21) wherein a tip of the inner tubular member engages the proximal end of the

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stent for advancing the stent toward the distal end of the outer tubular member as the release member moves toward the stabilizing member.

Regarding claims 26 and 27, the outer member moves back a specific distance to allow deployment of the stent, and this movement can be defined as having three positions, including a first position where the stent is not exposed, a second position where the stent is partially exposed, and a third position where the stent is further exposed.

Regarding claim 28, the outer tubular member is prevented from moving further proximally by the proximal portion of the housing, see Figure 5b, ref. 82.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6, 8-10, 12, 20-22, 24, and 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Derus.

Regarding claims 6 and 18, Derus discloses the claimed invention except for the amount of the stent exposed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to expose about 5 to about 95 percent of the stent since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

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Regarding claims 8, 20, and 29, Derus discloses insertion of an endoscope, or an elongated viewing device, slidably disposed in the outer tubular member (paragraph [0053]). While Derus does not specifically disclose the endoscope extending proximally of the proximal end of the outer tubular member, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the endoscope in a manner such that the proximal end of the viewing device extends outwardly of the proximal end of the outer tubular member in order to allow a user to engage the device with his or her eye, whereas if the proximal end of the endoscope did not extend proximal to the proximal end of the outer tubular member, the endoscope would require additional components for actual use.

Regarding claims 9, 21, and 30, Derus discloses means for releasably securing the viewing device with respect to the outer tubular member (106).

Regarding claims 10 and 22, the securing means is associated with the stabilizing member (see Figure 5b).

Regarding claims 12 and 24, Derus discloses the claimed invention except for threadingly attaching the clamp 106. It would have been an obvious matter of design choice to use a threaded clamp, since applicant has not disclosed that threading solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with any sort of clamp, such as a press-fit clamp or snap-fit clamp.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRIAN GRAHAM whose telephone number is (571)270-7484. The examiner can normally be reached on Monday - Friday 8:00 am-5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BJG/

December 5, 2009

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3734